#### **REMARKS**

#### I. Introduction

By the present Amendment, claims 1, 6, 10, 12, 13, 15, 18-20, 23, and 24 have been amended. Claims 21 and 22 have been cancelled. Accordingly, claims 1, 3, 6-20, 23, and 24 remain pending in the application. Claims 1, 23, and 24 are independent.

### II. Office Action Summary

In the Office Action of April 29, 2010, claims 1, 3, 6-9, 12, 13, 18, 20-22, and 24 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,132,373 issued to Ito et al. ("Ito '373"). Claims 10, 11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,353,220 issued to Ito et al. ("Ito '220"). Claim 14 was rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,615,680 issued to Sano. These rejections are respectfully traversed.

#### III. Rejections under 35 USC §102

Claims 1, 3, 6-9, 12, 13, 18, 20-22, and 24 were rejected under 35 USC §102(b) as being anticipated by Ito '373. Regarding this rejection, the Office Action indicates that Ito '373 discloses an apparatus for measuring an intima-media thickness of a blood vessel that includes a data analyzing device for receiving image data and calculating the intima-media thickness of the blood vessel according to the image data, and that the image data includes a plurality of luminance values that correspond to respective pixels of the image. The data analyzing device includes a setting device for setting a base position between a center of the blood vessel and a

position in the vicinity of an inner intima wall of the blood vessel on the image, a calculation device for detecting maximum and minimum values from among the luminance values corresponding to a predetermined number of pixels, and calculating the intima-media thickness based on the maximum and minimum values. The Office Action further indicates that the setting device calculates a moving average of the luminance values in the target part and sets a base position between the center of the blood vessel and the position in the vicinity of the inner intima wall of the blood vessel within the target part of the image. Ito '373 is further indicated as disclosing the adoption of a composite thickness of the tunica intima and media thickness as an index of judgment of arterial sclerosis. Applicants respectfully disagree.

As amended, independent claim 1 defines a medical imaging diagnostic apparatus that obtains image data from a blood vessel of an object being examined and measures the composite thickness of a tunica intima and a tunica media of the blood vessel. The medical imaging diagnostic apparatus comprises:

brightness distribution acquisition means for acquiring a brightness distribution in the thickness direction of a blood vessel wall in a tomogram with regard to the blood vessel,

setting means for setting the tunica intima reference point and the tunica externa reference point based on the brightness distribution,

extraction means for extracting pixels, with respect to each pixel in a setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range, and

calculation means for calculating a distance between a boundary in the blood vessel wall side in a region formed by the pixels being extracted based on the tunica intima reference point and a boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point.

The medical imaging diagnostic apparatus of independent claim 1 includes a brightness distribution acquisition means which acquires the brightness distribution in the thickness direction of a blood vessel wall in a tomogram with respect to the blood vessel, and a setting means which sets the tunica intima reference point and the tunica externa reference point based on the brightness distribution. An extraction means is provided for extracting pixels in the setting range including the tunica intima reference point or the tunica externa reference point wherein the brightness belongs to the setting range. A calculation means is also provided for calculating the distance between the boundary and the blood vessel wall side in the region formed by the pixels being extracted based on the tunica intima reference point and the boundary in the lumen side in the region formed by the pixels being extracted. This is done based on the tunica externa reference point.

The Office Action alleges that Ito '373 discloses all of the features recited in independent claim 1. This does not appear to be the case. Ito discloses an apparatus for measuring the intima-media thickness of a blood vessel wherein an ultrasound device is provided for outputting digital image data representing an image of the blood vessel produced by scanning with an ultrasound. A data analyzing device is provided for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. As discussed in the Background Section of the application, however, Ito '373 operates differently from the present invention. Applicants note that JP-A-99-318896 corresponds to Ito '373.

In conventional ultrasound apparatus for measuring intima media thickness, such as the one disclosed in Ito '373, the brightness distribution in the thickness direction of a blood vessel wall of image data in one line is obtained. The local

maximal point having the maximum brightness of the brightness distribution is then set as tunica externa reference point A. The second local maximal point that appears from tunica externa reference point A in the lumen side is set as tunica intima reference point B. The intima media thickness measurement is subsequently performed by setting a minimum point C that appears in the lumen side from tunica media reference point B as the inner wall of the lumen, as well as setting the midpoint between point D having the minimum brightness of the brightness distribution and tunica externa reference point A as the inner wall of the lumen. See paragraph [0004] of the published application. Thus, according to Ito '373, the tunica externa reference point and tunica intima reference point are set based on the brightness distribution in the thickness direction of the blood vessel wall based on one line of acquired image data. The intima media thickness measurement is subsequently performed in each line based on the tunic externa reference point and tunica intima reference point.

At least one problem associated with such techniques is that the minimum point C does not always appear clearly in the lumen side from the tunica media reference point in the brightness distribution of image data. Additionally, the midpoint between point D and tunica externa reference point A is set as the inner wall position of the tunica externa based on empirical rules obtained from factors such as clinical results. Due to the individual variability of objects being examined, there are cases that IMT cannot be measured accurately. See paragraph [0006].

In contrast, the present invention sets a range for the brightness of pixels to be extracted, thereby making it possible to extract the pixels corresponding to the lumen or tunica externa. Accordingly, the inner wall of the tunica intima or the inner wall of the tunica externa from the extracted pixel region can be accurately detected.

At least one benefit achieved by the invention defined by independent claim 1, is the ability to improve the accuracy with which the intima media thickness is measured by calculating the distance between the detected boundaries. Applicants' review of Ito has failed to reveal any disclosure or suggestion for such features.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 3 and 6-20 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

As amended, independent claim 24 defines a medical imaging diagnostic method that comprises:

acquiring a brightness distribution in the thickness direction of a blood vessel wall in a tomogram with regard to the blood vessel,

setting a tunica intima reference point and a tunica externa reference point based on the brightness distribution,

extracting pixels, with respect to each pixel in a setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range, and

calculating a distance between a boundary in the blood vessel wall side in a region formed by the pixels being extracted based on the tunica intima reference point and a boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point.

The medical imaging diagnostic method of independent claim 24 recites various steps that correspond to actions performed by the elements recited in independent claim 1. As previously discussed, Ito '373 calculates the intima media thickness in a manner that differs from that of the present invention.

It is therefore respectfully submitted that independent claim 23 is allowable over the art of record.

### IV. Rejections under 35 USC §103

Claims 10, 11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of "Ito '220. As previously discussed, claims 10, 11, 15-17, 19, and 23 depend from independent claim 1 and are therefore believed to be allowable over the art of record. Regarding claim 23, the Office Action asserts that Ito '373 discloses most of the features recited therein, except for three dimensional image data. Ito '220 is relied upon for disclosing a color three dimensional Doppler image data, wherein flow in a blood vessel is adopted as the object and a 3D color Doppler image is displayed by respective color reconstruction. The Office Action concludes that it would have been obvious to combine the two Ito references to obtain the tunica intima for the purpose of measuring the intima media thickness more accurately. Applicants respectfully disagree.

As amended, independent claim 23 defines a medical imaging diagnostic apparatus that comprises:

imaging means for obtaining image data related to a blood vessel of an object being examined;

Doppler imaging means for obtaining color Doppler image data related to the blood vessel;

brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data;

setting means for setting the tunica intima reference point and the tunica externa reference point based on the brightness distribution;

extraction means for extracting the pixels, with respect to each pixel in the setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range; and

calculating means for calculating the distance between the boundary in the blood vessel wall side in the region formed by the pixels being extracted based on the tunica intima reference point and the boundary in the lumen side in the region formed by the pixels being extracted based on the tunica externa reference point.

The medical imaging diagnostic apparatus of independent claim 23 includes an imaging means for obtaining image data related to a blood vessel or an object being examined, a Doppler imaging means for obtaining color Doppler image data related to the blood vessel, and a brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data. A setting means is provided for setting the tunical intima reference point and the tunica externa reference point based on the brightness distribution, and an extraction means is provided for extracting the pixels with respect to each pixel in the setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range. The medical imaging diagnostic apparatus further includes a calculating means for calculating the distance between the boundary in the blood vessel wall side in the region formed by the pixels being extracted based on the tunica intima reference point boundary in the lumen side in the region formed by the pixels being extracted based on the tunica externa reference point. As can be appreciated, the setting means, extraction means, and calculation means of independent claim 23 correspond somewhat to those recited in independent claim 1. As previously discussed, such features are not shown or suggested by the art of record. Furthermore, review of Ito '220 has failed to reveal any disclosure or suggestion for the features that are lacking from Ito '373.

It is therefore respectfully submitted that independent claim 23 is allowable over the art of record.

# V. Conclusion

For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

# <u>**AUTHORIZATION**</u>

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 529.46525X00).

Respectfully submitted,
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